

This listing of the claims will replace all prior versions, and listings, of claims in the application:

LISTING OF THE CLAIMS

Claim 1 (Currently amended). A method for treating premature ejaculation, which comprises systemically administering to a male individual in need of such treatment, [on an as-needed basis] less than 3.5 hours prior to anticipated sexual activity, a rapid-release pharmaceutical formulation containing a therapeutically effective amount of an antidepressant drug selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, monoamine oxidase inhibitors, azaspiron antidepressants, and atypical non-SRI antidepressants, wherein the formulation releases the drug at a rate that provides a systemically effective level of the drug within 3.5 hours of administration.

Claim 2 (Original). The method of claim 1, wherein the antidepressant drug is contained within a pharmaceutical formulation.

Claim 3 (Original). The method of claim 2, wherein the pharmaceutical formulation is a unit dosage form.

Claim 4 (Currently amended). The method of claim 2 [3], wherein the antidepressant drug is administered immediately prior to anticipated sexual activity.

Claim 5 (Currently amended). The method of claim 1 [4], wherein the antidepressant drug is administered about 0.25 to about 3.5 hours prior to anticipated sexual activity.

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Claim 6 (Currently amended). The method of claim 5, wherein the [active agent] antidepressant drug is administered about 0.5 to about 3.0 hours prior to anticipated sexual activity.

Claim 7 (Currently amended). The method of claim 6, wherein the [active agent] antidepressant drug is administered about 1 to about 2.5 hours prior to anticipated sexual activity.

Claim 8 (Original). The method of any one of claims 4, 5, 6 and 7, wherein the sexual activity is sexual intercourse.

Claim 9 (Original). The method of claim 2, wherein the formulation is an immediate release dosage form.

Claim 10 (Original). The method of claim 3, wherein the formulation is an immediate release unit dosage form.

Claim 11 (Currently amended). The method of claim [1] 2, wherein the [active agent] pharmaceutical formulation is administered orally.

Claim 12 (Original). The method of claim 11, wherein the pharmaceutical formulation is selected from the group consisting of tablets, capsules, caplets, solutions, suspensions, syrups, granules, beads, powders and pellets.

Claim 13 (Original). The method of claim 12, wherein the pharmaceutical formulation comprises a tablet.

Claim 14 (Original). The method of claim 12, wherein the pharmaceutical formulation comprises a capsule.

Claim 15 (Currently amended). The method of claim 1, wherein the [active agent] antidepressant drug is administered transmucosally.

Claim 16 (Currently amended). The method of claim 15, wherein the [active agent] antidepressant drug is administered sublingually.

Claim 17 (Currently amended). The method of claim 15, wherein the [active agent] antidepressant drug is administered buccally.

Claim 18 (Currently amended). The method of claim 15, wherein the [active agent] antidepressant drug is administered intranasally.

Claim 19 (Currently amended). The method of claim 15, wherein the [active agent] antidepressant drug is administered transurethrally.

Claim 20 (Currently amended). The method of claim 15, wherein the [active agent] antidepressant drug is administered rectally.

Claim 21 (Currently amended). The method of claim 1, wherein the [active agent] antidepressant drug is administered by inhalation.

Claim 22 (Currently amended). The method of claim 1, wherein the [active agent] antidepressant drug is administered transdermally.

Claim 23 (Original). The method of claim 1, wherein the active agent is administered parenterally.

Claim 24 (Original). The method of claim 1, wherein the antidepressant drug is selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressant drugs, and combinations thereof.

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Claim 25 (Currently amended). The method of claim 24, wherein the antidepressant drug is selected from the group consisting of amitriptyline, amoxapine, butriptyline, [clomipramine,] demexiptiline, desipramine, dibenzepin, dimetacrine, dothiepin, doxepin, imipramine, iprindole, lofepramine, maprotiline, melitracen, metapramine, mianserin, mirtazapine, nortryptiline,

propizepine, protriptyline, quinupramine, setiptiline, tianeptine, trimipramine, and combinations thereof.

Claims 26-27 (Currently canceled).

²⁸
Claim ~~28~~ (Currently amended). The method of claim 1, wherein the antidepressant drug is [selected from the group consisting of] a monoamine oxidase [inhibitors] inhibitor.

²⁷ ²⁶
Claim ~~29~~ (Currently amended). The method of claim ~~28~~, wherein the [antidepressant drug] monoamine oxidase inhibitor is selected from the group consisting of amiflamine, brofaromine, clorgyline, α-ethyltryptamine, iproclozide, iproniazid, isocarboxazid, mebanazine, moclobemide, nialamide, pargyline, phenelzine, pheniprazine, pirlindole, safrazine, selegiline, toloxatone, tranylcypromine, and combinations thereof.

²⁸
Claim ~~30~~ (Currently amended). The method of claim 1, wherein the antidepressant drug is [selected from the group consisting of] an azaspirone [antidepressants] antidepressant.

²⁹ ²⁸
Claim ~~31~~ (Currently amended). The method of claim ~~30~~, wherein the azaspirone antidepressant [drug] is selected from the group consisting of buspirone, gepirone, ipsapirone, tandospirone, tiaspirone, and combinations thereof.

³⁰
Claim ~~32~~ (Currently amended). The method of claim 1, wherein the antidepressant drug is an atypical non-SRI antidepressant selected from the group consisting of amesergide, amineptine, benactyzine, bupropion, fezolamine, levoprotiline, medifoxamine, mianserin, minaprine, oxaflozane, oxitriptan, rolipram, teniloxazine, tofenacin, trazodone, tryptophan, viloxazine, and combinations thereof.

³¹
Claim ~~33~~ (Original). The method of claim 1, further comprising administering at least one additional active agent with the antidepressant drug.

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Claim ~~34~~ (Original). The method of claim ~~33~~, wherein the additional active agent is a vasoactive agent selected from the group consisting of nitroglycerin, isosorbide dinitrate, erythrityl tetranitrate, amyl nitrate, sodium nitroprusside, molsidomine, linsidomine chlorhydrate, S-nitroso-N-acetyl-D,L-penicillamine, S-nitroso-N-cysteine and S-nitroso-N-glutathione, diazenium diolates ("NONOates"), phenoxybenzamine, dibenamine, doxazosin, terazosin, phentolamine, tolazoline, prazosin, trimazosin, alfuzosin, tamsulosin, indoramin, ergotamine, acetergamine, brazergoline, bromerguride, cianergoline, delorgotril, disulergine, ergonovine maleate, ergotamine tartrate, etisulergine, lergotril, lysergide, mesulergine, metergoline, metergotamine, nicergoline, pergolide, propisergide, proterguride, diazoxide, hydralazine, minoxidil nimodepine, pinacidil, cycloandelate, dipyridamole, isoxsuprine, chlorpromazine, haloperidol, yohimbine, prostaglandin E₀, prostaglandin E₁, prostaglandin A₁, prostaglandin B₁, prostaglandin F_{1α}, 19-hydroxy- prostaglandin A₁, 19-hydroxy- prostaglandin B₁, prostaglandin E₂, prostaglandin A₂, prostaglandin B₂, 19-hydroxy- prostaglandin A₂, 19-hydroxy- prostaglandin B₂, prostaglandin E₃, prostaglandin F_{3α}, carboprost tromethamine, dinoprost tromethamine, dinoprostone, lipoprost, gemeprost, metenoprost, sulprostone, tiaprost, vasoactive intestinal peptide, and combinations thereof.

33
Claim ~~35~~ (Original). The method of claim ~~33~~, wherein the additional active agent is a phosphodiesterase inhibitor.

34
Claim ~~36~~ (Original). The method of claim ~~35~~, wherein the phosphodiesterase inhibitor is a Type III, Type IV, Type V, or nonspecific phosphodiesterase inhibitor.

35
Claim ~~37~~ (Original). The method of claim ~~33~~, wherein the additional active agent is selected from the group consisting of cianopramine, citalopram, femoxetine, fluoxetine, fluvoxamine, ifoxetine, milnacipran, nomifensine, oxaprotiline, paroxetine, sertraline, sibutramine, venlafaxine, viqualine, zimeldine, clovoxamine, etoperidone, methylphenidate, nefazodone, opipramol, 2-methyl serotonin, lysergic acid diethylamide, ergot alkaloids, 8-hydroxy-(2-N,N-dipropylamino)-tetraline, 1-(4-bromo-2,5-dimethoxyphenyl)-2-aminopropane, cisapride, sumatriptan, *m*-chlorophenylpiperazine, zacopride, mezacopride, ondansetron, granisetron,

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metoclopramide, tropisetron, dolasetron, trimethobenzamide, methysergide, risperidone, ketanserin, ritanserin, clozapine, R(+)- (2,3-dimethoxyphenyl)-1-[2-(4-fluorophenyl)ethyl]-4-piperidine-methanol, azatadine, cyproheptadine, fenclonine, dexfenfluramine, fenfluramine, chlorpromazine, methoxamine, methpentamine, metaraminol, mitodrine, clonidine, apraclonidine, guanfacine, guanabenz, methyl dopa, amphetamine, methamphetamine, epinephrine, norepinephrine, ethylnorepinephrine, phenylephrine, ephedrine, pseudoephedrine, pemoline, naphazoline, tetrahydrozoline, oxymetazoline, xylometazoline, phenylpropanolamine, phenylethylamine, dopamine, dobutamine, colterol, isoproterenol, isotharine, metaproterenol, terbutaline, tyramine, hydroxyamphetamine, ritodrine, prenalterol, albuterol, isoetharine, pirbuterol, bitolterol, fenoterol, formoterol, procaterol, salmeterol, mephenterine, propylhexedrine, phenoxybenzamine, phentolamine, tolazoline, prazosin, terazosin, doxazosin, trimazosin, yohimbine, labetalol, urapidil, alfuzosin, bunazosin, tamsulosin, haloperidol, phenothiazines, butyrophenones, propranolol, nadolol, timolol, pindolol, metoprolol, atenolol, esmolol, acebutolol, bopindolol, carteolol, oxprenolol, penbutolol, carvedilol, medroxalol, naftopidil, bucindolol, levobunolol, metipranolol, bisoprolol, nebivolol, betaxolol, carteolol, celiprolol, sotalol, propafenone, indoramin, bethanidine, debrisoquine, guabenxan, guanadrel, guanazodine, guanethidine, guanoclor, guanoxan, alprazolam, brotizolam, chlordiazepoxide, clobazepam, clonazepam, clorazepate, demoxepam, diazepam, estazolam, flurazepam, halazepam, lorazepam, midazolam, nitrazepam, nordazepam, oxazepam, prazepam, quazepam, temazepam, triazolam, pharmacologically acceptable salts thereof, and combinations of any of the foregoing.

34
Claim ~~38~~³⁴ (Original). The method of claim ~~37~~³⁷, wherein the additional active agent is selected from the group consisting of alprazolam, brotizolam, chlordiazepoxide, clobazepam, clonazepam, clorazepate, demoxepam, diazepam, estazolam, flurazepam, halazepam, lorazepam, midazolam, nitrazepam, nordazepam, oxazepam, prazepam, quazepam, temazepam, triazolam, and pharmaceutically acceptable salts thereof.

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Claim ~~39~~ (Original). The method of claim ~~37~~, wherein the additional active agent is selected from the group consisting of fluoxetine, fluvoxamine, paroxetine, sertraline, and pharmaceutically acceptable salts thereof.

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Claim ~~40~~ (Currently amended). A pharmaceutical formulation for treating premature ejaculation, comprising a rapid-release [rapid release] formulation of a therapeutically effective amount of an antidepressant drug selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, MAO inhibitors, azaspiron antidepressants, and atypical non-SRI antidepressants, in an amount effective to delay the onset of ejaculation by the individual during sexual activity, and a pharmaceutically acceptable carrier, wherein the formulation releases the drug at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration to a patient.

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Claim ~~41~~ (Original). The formulation of claim ~~40~~, wherein the antidepressant drug is selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressant drugs, and combinations thereof.

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Claim ~~42~~ (Currently Amended). The formulation of claim ~~41~~, wherein the antidepressant drug is selected from the group consisting of amitriptyline, amoxapine, butriptyline, [clomipramine,] demexiptiline, desipramine, dibenzepin, dimetacrine, dothiepin, doxepin, imipramine, iprindole, lofepramine, maprotiline, melitracen, metapramine, mianserin, mirtazapine, nortriptyline, propizepine, protriptyline, quinupramine, setiptiline, tianeptine, trimipramine, and combinations thereof.

41
Claims 43-44 (Currently canceled).

43
Claim ~~45~~ (Original). The formulation of claim ~~40~~, wherein the antidepressant drug is selected from the group consisting of monoamine oxidase inhibitors.

~~42~~ ~~44~~ ~~45~~ ~~43~~ ~~41~~
Claim ~~46~~ (Original). The formulation of claim ~~45~~, wherein the antidepressant drug is selected from the group consisting of amiflamine, brofaromine, clorgyline, α -ethyltryptamine, iproclozide, iproniazid, isocarboxazid, mebanazine, moclobemide, nialamide, pargyline, phenelzine, pheniprazine, pirlindole, safrazine, selegiline, toloxatone, tranylcypromine, and combinations thereof.

~~43~~ ~~45~~ ~~38~~
Claim ~~47~~ (Original). The formulation of claim ~~40~~, wherein the antidepressant drug is selected from the group consisting of azaspirone antidepressants.

~~44~~ ~~46~~ ~~43~~ ~~45~~
Claim ~~48~~ (Original). The formulation of claim ~~47~~, wherein the antidepressant drug is selected from the group consisting of buspirone, gepirone, ipsapirone, tandospirone, tiaspirone, and combinations thereof.

~~47~~ ~~45~~ ~~38~~
Claim ~~49~~ (Original). The formulation of claim ~~40~~, wherein the antidepressant drug is an atypical non-SRI antidepressant selected from the group consisting of amesergide, amineptine, benactyzine, bupropion, fezolamine, levoprotiline, medifoxamine, mianserin, minaprine, oxaflozane, oxitriptan, rolipram, teniloxazine, tofenacin, trazodone, tryptophan, viloxazine, and combinations thereof.

~~48~~ ~~46~~ ~~38~~
Claim ~~50~~ (Original). The formulation of claim ~~40~~, in unit dosage form.

~~49~~ ~~47~~ ~~48~~ ~~46~~
Claim ~~51~~ (Original). The formulation of claim ~~50~~, wherein the antidepressant drug is present in an amount of about 0.1 mg to about to about 300 mg.

~~50~~ ~~48~~ ~~47~~ ~~49~~
Claim ~~52~~ (Currently amended). The formulation of claim ~~51~~, wherein the amount is in the range of about 1 mg to about 100 mg [100mg].

~~51~~ ~~49~~ ~~48~~ ~~50~~
Claim ~~53~~ (Original). The formulation of claim ~~52~~, wherein the amount is in the range of about 1 mg to about 50 mg.

~~50~~ ~~52~~ ~~38~~ ~~38~~
Claim ~~54~~ (Original). The formulation of claim ~~40~~, in the form of a rapidly disintegrating tablet.

~~51~~ ~~52~~ ~~38~~
Claim ~~55~~ (Original). The formulation of claim ~~40~~, in the form of an effervescent tablet.

~~52~~ ~~54~~ ~~38~~
Claim ~~56~~ (Original). The formulation of claim ~~40~~, in the form of an open matrix network tablet.

~~53~~ ~~55~~ ~~38~~
Claim ~~57~~ (Original). A formulation of claim ~~40~~, adapted for transmucosal drug administration, wherein the carrier is suitable for transmucosal drug delivery buccally, sublingually, intranasally, rectally, or by inhalation.

~~54~~ ~~56~~ ~~53~~ ~~55~~
Claim ~~58~~ (Original). The formulation of claim ~~57~~, comprising a solid dosage form for application to the buccal mucosa, and wherein the carrier is suitable for buccal drug delivery.

~~55~~ ~~57~~ ~~54~~ ~~56~~
Claim ~~59~~ (Original). The formulation of claim ~~58~~, wherein the carrier is a hydrolyzable polymer.

~~56~~ ~~58~~ ~~55~~ ~~57~~
Claim ~~60~~ (Original). The formulation of claim ~~59~~, wherein the dosage form further comprises an adhesive suitable for affixing the dosage form to the buccal mucosa.

~~57~~ ~~59~~ ~~53~~ ~~55~~
Claim ~~61~~ (Original). The formulation of claim ~~60~~, comprising a dosage form for application to the sublingual mucosa, and wherein the carrier is suitable for sublingual drug delivery.

~~58~~ ~~60~~ ~~53~~ ~~55~~
Claim ~~62~~ (Original). The formulation of claim ~~61~~, comprising a dosage form for application to the rectal mucosa, and the carrier is suitable for rectal drug delivery.

~~59~~ ~~61~~ ~~58~~ ~~60~~
Claim ~~63~~ (Original). The formulation of claim ~~62~~, comprising a rectal suppository.

~~60~~ ~~62~~ ~~53~~ ~~55~~
Claim ~~64~~ (Original). The formulation of claim ~~63~~, comprising a dosage form suitable for inhalation.

~~61~~ ~~63~~ ~~60~~ ~~62~~
Claim ~~65~~ (Original). The formulation of claim ~~64~~, comprising a liquid.

~~62~~ ~~64~~ ~~60~~ ~~62~~
Claim ~~66~~ (Original). The formulation of claim ~~64~~, comprising a dry powder.

~~63~~ ~~65~~ ~~60~~ ~~62~~
Claim ~~67~~ (Original). The formulation of claim ~~64~~, comprising an aerosol composition.

~~64~~ ~~66~~ ~~38~~
Claim ~~68~~ (Original). The pharmaceutical formulation of claim ~~40~~, comprising an intranasal solution.

~~65~~ ~~67~~ ~~38~~
Claim ~~69~~ (Original). The formulation of claim ~~40~~, in the form of a gum.

~~66~~ ~~68~~ ~~38~~
Claim ~~70~~ (Original). The formulation of claim ~~40~~, in the form of a transdermal drug delivery device adapted to be affixed to an individual's body surface.

~~67~~ ~~69~~
Claim ~~71~~ (Currently amended). A packaged kit for a patient to use in the treatment of premature ejaculation, comprising: a rapid-release pharmaceutical formulation of an antidepressant drug selected from the group consisting of tricyclic antidepressants, tetracyclic antidepressants, MAO inhibitors, azaspirone antidepressants, and atypical non-SRI antidepressants, wherein the formulation releases the drug at a rate effective to provide a systemically effective level of the drug within 3.5 hours of administration to a patient; a container housing the pharmaceutical formulation during storage and prior to administration; and instructions for carrying out drug administration in a manner effective to treat premature ejaculation.

~~68~~ ~~70~~ ~~67~~ ~~69~~
Claim ~~72~~ (Original). The packaged kit of claim ~~71~~, wherein the pharmaceutical formulation is a rapid-release dosage form containing a unit dosage of the antidepressant drug, the unit dosage being a therapeutically effective dosage for treatment of premature ejaculation.